

PROBIOTIC SOLUTIONS LIMITED

5553 West Island Highway, Qualicum Beach,

British Columbia, Canada. V9K 2C8

Phone: (250) 757-2046, Fax: (250) 757 2046

April 20, 1999

William K. Hubbard
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
USA

Dear William K. Hubbard,

Re: Federal Register Request for Information: Performance Standard for *Vibrio vulnificus*. Docket number 98P-0504 – Volume 64, Number 13, Page 3300-3301

The FDA has requested information on eight points of interest in regards to issues raised by a petition submitted by the Center for Science in the Public Interest. This letter aims to address some of these points.

As an introduction, at Probiotics Solutions Limited, we are involved in the development and production of beneficial strains of bacteria "probiotics" against disease causing bacteria in fish and shellfish.

Such probiotics are already widely used in both poultry and animal farming to control the occurrence of pathogenic bacteria. We have successfully used such probiotics in the production of juvenile shellfish such as geoduck, oysters and scallops.

The use of such probiotics present an alternative and cost effective method to reduce or eliminate the incidence of pathogenic species of *Vibrios* in raw shellfish.

I urge the FDA to explore the use of this technology in setting performance standards for shellfish. We have demonstrated successes in this regard and we are available to assist the FDA in this regard.

Sincerely,



Dr. Abayomi O. Alabi

98P-0504

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Answers to FDA's Eight Questions (From the Federal Register)

1. The Ameripure Co. technology is not readily employable by the shellfish industry. This is because of the high costs involved. If this technology were employed, large numbers of shellfish businesses would be forced out of operation.
2. There is a technological process involving the use of "probiotics", beneficial bacterial species from the autochthonous bacterial community. The probiotics restrict the growth and development of the pathogens. Similar technology is currently used in poultry farming where new chicks are inoculated with a broth of probiotics that restrict the growth of Salmonella. Use of this type of technology would still retain the sensory qualities of the raw oysters.
3. References to the efficacy of probiotic use in bivalves include the Pacific oyster, (Douillet and Langdon, 1993; 1994) and the Chilean scallop (Riquelme et. al., 1996, 1997). Probiotic Solutions Limited has also produced probiotics which have been successfully used in culture of larval and juvenile geoduck, oysters and scallops. The efficacy of this type of technology is also attested to by their wide spread and increasing use in land based agriculture to control diseases caused by such pathogenic bacteria. In addition, use of this technology would be more cost effective than pasteurization.
4. At present, there is inadequate knowledge to determine what constitutes an appropriate performance level.
5. There is no requirement to establish a performance standard for shellfish without first establishing that they pose a public health threat.
6. There is no way at present to determine the quantifiable and non-quantifiable costs of setting a performance standard. It is reasonable to assume that the majority of such costs would be borne by the shellfish industry while some will be shifted to the final consumer. Costs would be expected to increase still more if a standard of undetectable was applied.
7. Using Ameripure's patented system as the only standard would result in the creation of a monopoly and Ameripure would be the beneficiary of such a policy requiring standards.
8. Currently, there is no science in place to determine what constitutes an infectious level for *V. parahaemolyticus*. If this were in place, then application of a performance standard might be justified.

Sincerely,



Dr. Abayomi O. Alabi

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Literature cited:

Douillet, P.A. and Langdon, C.J. (1993) Effects of Marine bacteria on the culture of axenic oyster *Crassostrea gigas* (thunderg) Larvae. Biological Bulletin 184: 36-51.

Douillet, P.A. and Langdon, C.J. (1994) Use of a probiotic for the culture of larvae of the pacific oyster (*Crassostrea gigas* Thunberg). Aquaculture 119:25-40.

Riquelme, C., Hayashida, G., Araya, R., Uchida, A., Satomi, M. and Ishida, Y. (1996) Isolation of a native bacterial strain from the scallop *Argopecten purpuratus* with inhibitory effects against pathogenic vibrios. Journal of Shellfish Research 15(2):369-372.

Riquelme, C., Araya, R., Vergara, N., Rojas, A., Guaita, M. and Candia, M (1997) Potential probiotic strains in the culture of the Chilean scallop *Argopecten purpuratus* (Lamarck, 1819). Aquaculture 154:17-26.